

## EXAMINER'S CASE ACTION WORKSHEET

Application No. 09/822,299		Legal Instrument Examiner
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CHECK TYPE OF ACTION

DATE OF COUNT

<input checked="" type="checkbox"/> Non-Final Rejection	<input type="checkbox"/> Restriction/Election Only	<input type="checkbox"/> Final Rejection
<input type="checkbox"/> Ex Parte Quayle	<input type="checkbox"/> Allowance	<input type="checkbox"/> Advisory Action
<input type="checkbox"/> Examiner's Answer	<input type="checkbox"/> Reply Brief Noted	<input type="checkbox"/> Non-Entry of Reply Brief
<input type="checkbox"/> Defective Notice of Appeal	<input type="checkbox"/> Interference Disposal SPE _____ (Approval for Disposal)	<input type="checkbox"/> Suspension (Examiner-Initiated) SPE _____ (initial)
<input type="checkbox"/> Defective Appeal Brief	<input type="checkbox"/> SIR Disposal (use only after FAOM)	<input type="checkbox"/> Supplemental Examiner's Amendment
<input type="checkbox"/> Miscellaneous Office Letter (With Shortened Statutory Period Set)	<input type="checkbox"/> Notice of Non-Responsive Amendment (With One Month Time Period set)	<input type="checkbox"/> Miscellaneous Office Letter (No Response Period Set)
<input type="checkbox"/> Abandonment after BPAI Decision	<input type="checkbox"/> Supplemental Action (excluding Examiner's Answer)	<input type="checkbox"/> Response to Rule 312 Amendment
<input type="checkbox"/> Letter Restarting Period for Response (e.g., Missing References)	<input type="checkbox"/> Interview Summary	<input type="checkbox"/> Authorization to Change Previous Office Action SPE: _____ (Initial)
<input type="checkbox"/> Abandonment	<input type="checkbox"/> Express Abandonment Date: _____	<input type="checkbox"/> Other Specify: _____

Examiner's Name: Laurie Mayes

AU: 1653



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,299	03/22/2001	Graham McCreathe	8117-15	8043

23973 7390 04/10/2003

DRINKER BIDDLE & REATH  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

EXAMINER

MAYES, LAURIE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/822,299	MCCREATH, GRAHAM
	<b>Examiner</b>	<b>Art Unit</b>
	Laurie Mayes	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 26 February 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election***

Applicant's election of Group I, claims 1-25 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 26-34 and 36-38 are non-elected claims and will not be examined.

### ***Information Disclosure Statement***

The information disclosure statement filed October 1, 2002, paper # 7, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been considered as to documents AA and AB. Document AC has not been considered because no copy of the document was with the application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-9, 13-18, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staples et al. (US 5,169,936) in view of WO 95/22258. Staples et al. teach that fibrinogen is a protein having surface metal-binding amino acid residues (claim 15, col. 11,

line 61), a method for obtaining a protein, in high yield (col. 2, lines 22-24), having surface metal-binding amino acid residues (col. 11, line 61) from a solution with pH of 5.5 (col. 8, line 66) wherein the solution is contacted with a cation exchange chromatography substrate (S-Sepharose, col. 8, lines 68 to col. 9, line 1)(present claim 1, 17) under conditions where the pH is about 8.5 (col. 6, line 58)(present claim 6) and the protein binds to the substrate (col. 7, lines 1-14) and removing the protein by using a salt, KCl (col. 4, lines 55-57)(present claim 1) or Tris.HCl buffer at pH 8.5 containing NaCl (col. 9, lines 3-5), wherein the protein yield is at least 60% (col. 6, lines 63-65)(claims 2 and 18), wherein the irrigating buffer of 0.05-1.0 M has a pH of 8.5 (col. 6, lines 41-43)(present claims 7, 8), wherein the substrate is in a column format (col. 5, lines 46-47)(present claims 13 and 22) and the cation exchange media is by fixed bed adsorption (col. 8, lines 65-69 and col. 9, lines 1-7)(present claims 14 and 23), wherein the protein may be human fibrinogen (col. 11, line 61)(present claims 1, 16, 25), wherein the method for obtaining the protein comprises ion exchange chromatography (col. 10, lines 60-68)(present claim 17). Staples et al. do not teach a method for obtaining fibrinogen from milk specifically.

WO 95/22258 teaches an efficient and economical (p. 6, line 17) method of obtaining lactoferrin from milk comprising contacting milk with a cation exchange chromatography substrate (p. 7, lines 12-14) under conditions where the lactoferrin is bound to the substrate (p. 7, lines 20-21) and wherein the cation exchange media is by fixed bed adsorption (p. 30, lines 18-22)(present claims 14 and 23), washing the substrate (p. 7, line 23), removing the bound lactoferrin by using irrigating means (NaCl or KCl) with a pH of 7.5 which is greater than the pI of fibrinogen (5.5)(present claim 1), wherein the milk is whole milk (p. 34, line 22)(present claim 9) and wherein the protein is transgenic (p. 1, lines 5-10)(present claims 15, 24). WO

95/22258 does not teach the removal of fibrinogen from milk. Given the advantages of the method of Staples et al. of obtaining a high yield of purified fibrinogen from a solution and the economical and efficient method of purifying proteins from milk taught by WO 95/22258, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a cation exchange chromatography method to purify fibrinogen from milk with high yields and in an economical and efficient manner. Thus, the claimed invention was *prima facie* obvious to make and use at the time the claimed invention was made.

Claims 1, 3-6, 10-12, 17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staples et al.) in view of WO 95/22258 and in further view of WO 96/02571 (French language)(and subsequent US Patent Number 5,834,420, in English). WO 95/22258 teaches a method of protein purification from milk wherein casein is removed because casein may interfere with the efficient purification of the protein by strong cation exchange chromatography (p. 15, lines 28-36 and p. 16, lines 1-5). However, neither Staples et al. nor WO 95/22258 teach a method wherein the contacting the milk with a chromatography substrate where the pH is around 6.0. WO 96/02571 teaches a method of obtaining fibrinogen from a liquid (see abstract) comprising contacting the liquid with a chromatography substrate (col. 6, line 40-46) at an advantageous pH around 6.0 to obtain a purified concentration (col. 4, line 66 and col. 3, lines 32-36)(present claims 3-5), removing the fibrinogen by an irrigation means with a pH of around 7 (col. 5, lines 5-17)(present claim 6) and wherein casein is removed by citrate (col. 4, line 65 and col. 6, lines 29-31). Given the advantages of the method of Staples et al. of obtaining a high yield of purified fibrinogen from a solution using cation exchange chromatography and the economical and efficient method of purifying proteins from milk taught

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by WO 95/22258, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a cation exchange chromatography method to purify fibrinogen from milk at the advantageous pH and to remove casein using EDTA and/ or citrate as taught by WO 96/02571 for resulting high yields in an economical and efficient manner. Thus, the claimed invention was *prima facie* obvious to make and use at the time the claimed invention was made.

### ***Conclusion***

**No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 7 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

*L. Mayes*  
Laurie Mayes  
Patent Examiner  
Art Unit 1653  
April 4, 2003

*Christopher S. F. Low*  
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